



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 522, 524, and 558

[Docket No. FDA-2012-N-0002]

New Animal Drugs; Butorphanol; Doxapram; Triamcinolone; Tylosin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal approval of a new animal drug application (NADA) and three abbreviated new animal drug applications (ANADAs) at the sponsors' request because the products are no longer manufactured or marketed.

DATES: This rule is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

David Alterman,
Center for Veterinary Medicine (HFV-212),
Food and Drug Administration,
7519 Standish Pl.,
Rockville, MD 20855,
240-453-6843,
email: david.alterman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The sponsors of the NADA and ANADAs listed in

table 1 have requested that FDA withdraw approval because the products are no longer manufactured or marketed:

Table 1--NADA and ANADAs for Which Withdrawal of Approval Has Been Requested

NADA/ANADA Number	Trade Name (drug)	Applicant	Citation in 21 CFR
100-556	Vigorena Feeds Hy-Ty Premix (tylosin phosphate)	Springfield Milling Corp., Vigorena Feeds, Springfield, MN 56087	558.625
200-435	RESPIRAM (doxapram hydrochloride) Injection	Modern Veterinary Therapeutics, LLC 18001 Old Cutler Rd., suite 317, Miami, FL 33157	522.775
200-446	BUTORPHINE (butorphanol tartrate) Injection	Modern Veterinary Therapeutics, LLC 18001 Old Cutler Rd., suite 317, Miami, FL 33157	522.246
200-459	VETAZINE (triamcinolone) Cream	Modern Veterinary Therapeutics, LLC 18001 Old Cutler Rd., suite 317, Miami, FL 33157	524.2483

Elsewhere in this issue of the Federal Register, FDA gave notice that approval of NADA 100-556 and ANADAs 200-435, 200-446, and 200-459, and all supplements and amendments thereto, is withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these voluntary withdrawals of approval.

Following these withdrawals of approval, Modern Veterinary Therapeutics, LLC, and Springfield Milling Corp. will no longer be the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for these firms.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 522 and 524

Animal drugs.

21 CFR Parts 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 522, 524, and 558 are amended as follows:

PART 510--NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. In § 510.600, in the table in paragraph (c)(1), remove the entries for “Modern Veterinary Therapeutics, LLC” and “Springfield Milling Corp.”; and in the table in paragraph (c)(2), remove the entries for “015914” and “035955”.

PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.246 [Amended]

4. In § 522.246, in paragraph (b)(2), remove “Nos. 015914 and 059130” and in its place add “No. 059130”.

§ 522.775 [Amended]

5. In § 522.775, in paragraph (b), remove “Nos. 000010 and 015914” and in its place add “No. 000010”.

PART 524--OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

6. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.2483 [Amended]

7. In § 524.2483, in paragraph (b), remove “015914,”.

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

8. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.625 [Amended]

9. In § 558.625, remove and reserve paragraph (b)(40).

Dated: September 27, 2012

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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